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10/590,038	11/17/2006	Edward Zbygniew Nowak	061170-0235	5625

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

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06/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,038	NOWAK, EDWARD ZBYGNIEW	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18-26 and 28-40* is/are pending in the application.

4a) Of the above claim(s) *1-3,5-15,29 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16, 18-26, 28, 30-35 and 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the arguments filed on 03/30/2009.

2. Claims 16, 18-26, 28, 30-35 and 37-39 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 03/30/2009 regarding the rejection of claim 19, 24 and 35 made by the Examiner under 35 USC 112, second paragraph have been fully considered and they are found persuasive. This argument has been overcome by Applicants clarification.

4. Applicants arguments filed 03/30/2009 regarding the rejection of claims 16, 18-20, 23, 24, 26, 28, 31, 35 and 40 made by the Examiner under 35 USC 102(b) over Inaba et al. (US 4552751) have been fully considered but they are not persuasive.

5. The rejection of claims 16, 18-20, 23, 24, 26, 28, 31, 35 and 40 made by the examiner under 35 USC 102(b) is **MAINTAINED** for the reasons of record in the office action mailed on 09/30/2008.

6. In regards to the 102(b) rejection, Applicant asserts the following:

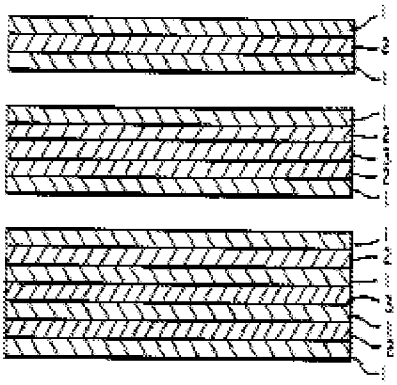
A) Inaba prepares a multi-layered film by creating multiple film-formed layers using either a drug release controlling layer solution or a drug storing layer solution;

B) Inaba teaches different compositions and therefore different structures; and

C) Claim 40 should not be rejected because Inaba is not seen to disclose or suggest a non-gelatin polymeric film that include two or more bands with at least one active ingredient dispersed within a particular band.

7. In response to A, the Examiner does not understand the distinction Applicant is trying to make. The instantly claimed film does not preclude a multi-layer film. Moreover the active steps of making a film as taught by Inaba are the same as that instantly claimed. As was noted in the previous office action, the process of making the film requires casting a drug-free film layer followed by applying a drug containing solution and letting said solution dry on the film. The films used by Inaba do not possess any gelatin. It's not clear how Applicants method is different from the method disclosed by the reference. Applicants argument is not persuasive.

8. In response to B, this argument is not clear to the Examiner either. The composition is not different. The only material limitations present in the instant claims are that the films do not contain gelatin and have a drug associated with the casted film. Inaba teaches a process for making a film wherein the film does not possess gelatin. Its' not clear to the Examiner how the composition of Inaba is any different from the compositions as claimed, let alone how the structure of the resultant composition would be any different, especially in view of the identical method steps. Applicants argument is not persuasive.

9. In response to C, this argument is not persuasive. Inaba teaches that the films as having the following structure:  wherein layer 1 corresponds to a drug release controlling layer and layers 2 and 3 correspond to drug storing layers (see abstract). Thus, the film has at least two bands with at least one active agent being dispersed within a particular band. While having multiple layers, the film is homogenous as each layer is casted together to form a continuous structure.

10. Applicants arguments filed 03/30/2009 regarding the rejection of claims 25 and 32 made by the Examiner under 35 USC 103(a) over Inaba in view of Fagen et al. (US 2003/0183643) have been fully considered but they are not found persuasive.

11. The rejection of claims 25 and 32 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 09/30/2008.

12. In regards to the 103(a) rejection, Applicant asserts the following:

D) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

13. In response to D, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as a anticipatory reference, see the Examiners response to assertions B-D

14. Applicants arguments filed 03/30/2009 regarding the rejection of claims 21, 22 and 37-39 made by the Examiner under 35 USC 103(a) over Inaba in view of Patel et al. (US 2004/0253434) have been fully considered but they are not found persuasive.

15. The rejection of claims 21, 22 and 37-39 made by the examiner under 35 USC 103(a) is In regards to the 103(a) rejection, Applicant asserts the following:

E) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

16. In response to E, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as a anticipatory reference, see the Examiners response to assertions B-D

17. Applicants arguments filed 03/30/2009 regarding the rejection of claim 30 made by the Examiner under 35 USC 103(a) over Inaba in view of Brown et al. (US 6783768) have been fully considered but they are not found persuasive.

18. The rejection of claim 30made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 09/30/2008.

19. In regards to the 103(a) rejection, Applicant asserts the following:

F) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

20. In response to F, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as a anticipatory reference, see the Examiners response to assertions B-D

21. Applicants arguments filed 03/30/2009 regarding the rejection of claims 33 and 34 made by the Examiner under 35 USC 103(a) over Inaba in view of Fagen and Lynn et al. (US 7112361) have been fully considered but they are not found persuasive.

22. The rejection of claim indicate claims made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 09/30/2008.

23. In regards to the 103(a) rejection, Applicant asserts the following:

G) The anticipatory rejection over Inaba is inadequate therefore the obviousness rejections including Inaba are inadequate.

24. In response to G, the Examiner respectfully disagrees. For detailed reasons why Inaba is not inadequate as a anticipatory reference, see the Examiners response to assertions B-D

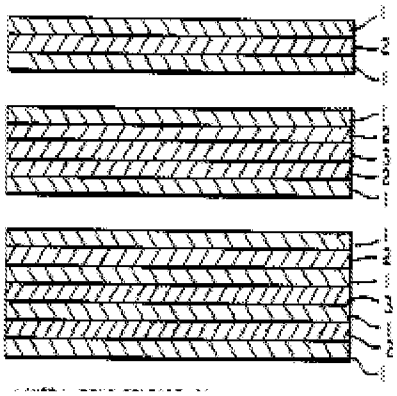
Maintained Rejections, of Record
Claim Rejections - 35 USC § 102

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

26. **Claims 16, 18-20, 23, 24, 26, 28, 31, 35 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Inaba et al. (US 4552751)**.

27. Inaba is directed to long-lasting multi-layered film preparations. The structure of the films are disclosed to have the following structures:



(see abstract).

Layer 1 corresponds to a drug release controlling layer and Layers 2 and 3 correspond to drug storing layers. The multilayered dosage forms are gelatin free. The polymers used in the films include hydroxypropyl methylcellulose and polyvinylpyrrolidone (see column 2, line 15). The method of making such films is as follows: A) make a drug-free film layer liquid formulation; B) cast A to form the film; C) make a drug-containing film layer liquid formulation; D) pour drug film liquid onto film A and let dry; and E) repeat indefinitely until desired dosage form has been prepared (see column 5, lines 10-20 and Example 1; see instant claims 16, 23, 24, 26, 28, 31, 35 and 40). It is noted that Applicants definition of monolith is simply a multi-layered dosage form. It should be pointed out that as one layer is drug free and one layer contains drug, there is necessarily a concentration gradient present in the film (see instant claim 18). Because the references multi-layered film compositions are identical to the instant claims, the final film would inherently have a homogenous structure.

28. The instant claims are product-by-process claims and are not limited to the manipulations of the recited steps, only the structure implied by those steps. So although Inaba may slightly differ in their process of making such films, the final product anticipates the instantly claim films.

29. Therefore, Inaba properly anticipates the instantly rejected claims.

Claim Rejections - 35 USC § 103

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

31. **Claims 25 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view of Fagen et al. (US 2003/0183643).**

32. Inaba is relied upon for disclosure described in the rejection of claims 16 under 35 U.S.C. 102(b).

33. Inaba teaches a multilayered film which possess five layers (see Example 5 and claim 11; see instant claim 32). Moreover, Figure 1 illustrates a film form which has 7 layers.

34. Inaba fails to teach the film being packaged to form a dose unit.

35. Fagen cures this deficiency. Fagen is directed to packaging of films such that individual sheets of the film are dispensed one at a time (see [0001]; see instant claim 25). It is taught that the packaging is useful because it protects unused products during repeated opening and closing (see [0005]).

36. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Inaba and Fagen to arrive a product wherein the films are packaged to form a unit dose. One would have been motivated to package the unit doses of the films disclosed by Inaba because it would protect the unused films thereby

preventing exposure to moisture and potential environmental degradation of the drug and/or film. Therefore, a packaged unit dose of a drug loaded non-gelatin film is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

37. **Claims 21, 22 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view of Patel et al. (US 2004/0253434).**

38. Inaba is relied upon for disclosure described in the rejection of claims 16 and 18-20 under 35 U.S.C. 102(b).

39. Inaba fails teach the film as being coiled or zigzag.

40. Patel cures these deficiencies. Patel is directed to water-soluble films systems with actives entrapped therein (see abstract). It is disclosed that the films can be in a rolled (i.e. coiled) or fanfold form (i.e. zigzag shape) (see [0197] and page 3). It is taught that such a shape is useful to selectively entrap interacting/non-interacting materials and their combinations (see abstract).

41. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Inaba and Patel with a reasonable expectation for success in arriving at a film composition wherein the film is in a coiled or zigzag shape. Inaba is discussed above. Briefly, Inaba discloses a non-gelatin film that has an drug solution applied to it and subsequently cured. Inaba fails to teach the shape of the film. Patel cures these deficiencies. Patel teaches that their water-soluble films are capable of being shaped into coiled or zigzag forms. One would have been motivated to shape the films to such forms because it

would aid in entrapping interacting and non-interacting materials. Moreover, such shapes would provide a more compact and convenient means for retaining the film material. Therefore, a non-gelatin film in the shape of a coil or zigzag is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

42. **Claims 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view Brown et al. (US 6783768).**

43. Inaba is relied upon for disclosure described in the rejection of claim 16 under 35 U.S.C. 102(b).

44. Inaba fails to teach the film as being employed to coat tablets or capsules.

45. Brown cures these deficiencies. Brown is directed to coating tablet cores with pharmaceutically active films (see abstract). The coating may be applied electrostatically or by inkjet (see column 16, lines 20-25). It is taught that such coatings can help to reduce the size of the dosage form as well as to minimize variation in the dose delivered (see column 1- column 2).

46. Therefore, it would have be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Inaba and Brown with a reasonable expectation for success in arriving at a film capable of coating a tablet. One would have been motivated to coat a tablet or capsule with the film of Inaba because it would reduce the size of the dosage form by minimizing the amount of inert ingredients as well as help to reduce the variation in the dosage delivered. Therefore, a tablet or capsule coated with a drug containing non-gelatin film is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

47. **Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view Fagen et al. (US 2003/0183643) and Lynn et al. (US 7112361).**

48. Inaba and Fagen is relied upon for disclosure described in the rejection of claim 25 under 35 U.S.C. 102(b).

49. Inaba and Fagen fail to teach the number of layers on the monolith as being greater than 10.

50. Lynn cures this deficiency. Lynn is directed to decomposable films containing polyelectrolytes. It is taught that the films can contain pharmaceutical actives. Lynn teaches a film which has 10 bilayers, wherein each bilayer comprises of poly(b-amino ester) and poly(sodium 4-styrenesulfonate). Thus, the final film has 20 layers (see instant claims 33 and 34). It is taught that the number of layers controls the release rate of the entrapped substances, i.e. a drug (see column 11, line 25).

51. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Inaba, Fagen and Lynn with a reasonable expectation for success in arriving at a multilayered film composition which comprises more than 10 layers. Inaba suggests such a composition by teaching that multi-layered dosage form is to have at least one drug storing layer and at least two drug releasing layers. Furthermore, Inaba teaches a composition which has 7 layers. Based on the teaching of Inaba one would have been motivated to make a film composition having multiple layers. If such a result was a film product that had 10 layers, then that would be a product of ordinary skill and common sense because

Inaba indirectly suggests making such a composition. Regardless, Inaba fail to explicitly teach a multilayered film having at least 10 layers. Lynn cures this deficiency. Lynn teaches a multilayer film formulation that can have up to 20 layers. One would have been motivated to modify the teaching of Inaba because in doing so would result in adjusting the release rate of the drugs from the dosage form. Therefore, a non-gelatin film possessing more than 10 layers is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

52. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

53. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

54. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

55. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

56. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
June 24, 2009

/David J Blanchard/
Primary Examiner, Art Unit 1643